IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:) Group Art Unit: 3737
Hassan MOSTAFAVI) Examiner: Lauritzen, Amanda L.
Serial No.: 10/655,920)
Filed: September 5, 2003)
For: SYSTEMS AND METHODS FOR GATING MEDICAL PROCEDURES)))

AMENDMENT & RESPONSE TO OFFICE ACTION

Mail Stop: AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed on October 18, 2007, Applicant hereby respectfully submits the following remarks.

Amendments to the Claims begin on page 2.

Remarks begin on page 15.

AMENDMENTS TO THE CLAIMS

Please cancel claim 30 without prejudice to pursue this claim in related application(s), and amend claims 24, 31, 34, and 40, as follow. A complete listing of the claims is provided below.

1. (Previously Presented) A method of performing physiological gating in a medical procedure, comprising:

acquiring a sequence of images, the sequence of images comprises at least a first image and a second image of a target region, wherein one of the first and second images is a real-time image;

determining a first composite image based on the first and second images; and gating a medical procedure based on the first composite image.

- 2. (Original) The method of claim 1, wherein the determining comprises subtracting the first image from the second image.
- 3. (Original) The method of claim 1, further comprising determining a first value associated with a contrast of the first composite image.
- 4. (Original) The method of claim 3, wherein the gating the medical procedure is performed based at least on the first value.

- 5. (Original) The method of claim 4, wherein the gating comprises de-activating a radiation beam when the first value is above a prescribed threshold value.
- 6. (Original) The method of claim 1, wherein the medical procedure comprises a radiation treatment procedure.
- 7. (Original) The method of claim 1, further comprising:
 acquiring a third image of the target region;
 determining a second composite image based on the second and third images; and
 gating the medical procedure based on the second composite image.
- 8. (Original) The method of claim 1, wherein the sequence of images are fluoroscopic images.
- 9. (Original) The method of claim 1, wherein the sequence of images are real-time images created during a session.
- 10. (Previously Presented) A system for performing physiological gating in a medical procedure, comprising:

means for acquiring a sequence of images, the sequence of images comprises at least a first image and a second image of a target region, wherein one of the first and second images is a real-time image;

means for determining a first composite image based on the first image and the second image; and

means for gating a medical procedure based on the first composite image.

- 11. (Original) The system of claim 10, further comprising means for determining a first value associated with a contrast of the first composite image.
- 12. (Original) The system of claim 11, wherein the means for gating the medical procedure performs the gating based at least on the first value.
- 13. (Original) The system of claim 12, wherein the means for gating comprises means for deactivating a radiation beam when the first value is above a prescribed threshold value.
- 14. (Original) The system of claim 10, wherein the medical procedure comprises a radiation treatment procedure.
- 15. (Previously Presented) A computer readable medium having a set of stored instructions, the execution of which causes a process to be performed, the process comprising:

acquiring a sequence of images, the sequence of images comprises at least a first image and a second image of a target region, wherein one of the first and second images is a real-time image;

determining a first composite image based on the first and second images; and

gating a medical procedure based on the first composite image.

- 16. (Original) The computer readable medium of claim 15, wherein the determining comprises subtracting the first image from the second image.
- 17. (Original) The computer readable medium of claim 15, wherein the process further comprising determining a first value associated with a contrast of the first composite image.
- 18. (Original) The computer readable medium of claim 17, wherein the gating the medical procedure is performed based at least on the first value.
- 19. (Original) The computer readable medium of claim 18, wherein the gating comprises deactivating a radiation beam when the first value is above a prescribed threshold value.
- 20. (Original) The computer readable medium of claim 15, wherein the medical procedure comprises a radiation treatment procedure.
- 21. (Original) The computer readable medium of claim 15, wherein the process further comprising:

acquiring a third image of the target region;

determining a second composite image based on the second and third images; and gating the medical procedure based on the second composite image.

- 22. (Original) The computer readable medium of claim 15, wherein the sequence of images are fluoroscopic images.
- 23. (Original) The computer readable medium of claim 15, wherein the sequence of images are real-time images created during a session.
- 24. (Currently Amended) A method of performing a medical procedure, comprising:

 providing a plurality of templates, each of the templates having an image and treatment data, wherein the treatment data comprises radiation treatment data;

acquiring an input image;

registering the input image with one of the templates; and

performing a medical procedure based on the treatment data of the one of the templates that is registered with the input image.

- 25. (Original) The method of claim 24, wherein the registering comprises selecting a template from the plurality of templates that best matches an image in the input image.
- 26. (Original) The method of claim 24, further comprising enhancing a moving object in the input image.

- 27. (Original) The method of claim 26, wherein the enhancing comprises determining a composite image of previously acquired input images.
- 28. (Original) The method of claim 27, wherein the determining a composite image comprises performing an image averaging on the previously acquired input images.
- 29. (Original) The method of claim 27, wherein the enhancing further comprises subtracting the composite image from the input image.
- 30. (Canceled)
- 31. (Currently Amended) The method of claim 30 24, wherein the radiation treatment data comprises one or a combination of beam-on signal, beam-off signal, beam-on duration, beam shape data, and dosage data.
- 32. (Original) The method of claim 24, wherein the medical procedure comprises directing a radiation beam to an object.
- 33. (Original) The method of claim 32, wherein the performing the medical procedure comprises adjusting a delivery of the radiation beam based on the treatment data.
- 34. (Currently Amended) A system for performing a medical procedure, comprising:

means for providing a plurality of templates, each of the templates having an image and treatment data, wherein the treatment data comprises radiation treatment data;

means for acquiring an input image;

means for registering the input image with one of the templates; and
means for performing a medical procedure based on the treatment data of the one of the
templates that is registered with the input image.

- 35. (Original) The system of claim 34, wherein the means for registering comprises means for selecting a template from the plurality of templates that best matches an image in the input image.
- 36. (Original) The system of claim 34, further comprising means for enhancing a moving object in the input image.
- 37. (Original) The system of claim 34, wherein the radiation treatment data comprises one or a combination of beam-on signal, beam-off signal, beam-on duration, beam shape data, and dosage data.
- 38. (Original) The system of claim 34, wherein the means for performing a medical procedure comprises means for directing a radiation beam to an object.

- 39. (Original) The system of claim 38, wherein the means for directing a radiation beam comprises means for adjusting a delivery of the radiation beam based on the treatment data.
- 40. (Currently Amended) A computer readable medium having a set of stored instructions, the execution of which causes a process to be performed, the process comprising:

providing a plurality of templates, each of the templates having an image and treatment data, wherein the treatment data comprises radiation treatment data;

acquiring an input image;

registering the input image with one of the templates; and

performing a medical procedure based on the treatment data of the one of the templates that is registered with the input image.

- 41. (Original) The computer readable medium of claim 40, wherein the registering comprises selecting a template from the plurality of templates that best matches an image in the input image.
- 42. (Original) The computer readable medium of claim 40, wherein the process further comprising enhancing a moving object in the input image.
- 43. (Original) The computer readable medium of claim 42, wherein the enhancing comprises determining a composite image of previously acquired input images.

- 44. (Original) The computer readable medium of claim 43, wherein the determining a composite image comprises performing an image averaging on the previously acquired input images.
- 45. (Original) The computer readable medium of claim 43, wherein the enhancing further comprises subtracting the composite image from the input image.
- 46. (Original) The computer readable medium of claim 40, wherein the radiation treatment data comprises one or a combination of beam-on signal, beam-off signal, beam-on duration, beam shape data, and dosage data.
- 47. (Original) The computer readable medium of claim 40, wherein the medical procedure comprises directing a radiation beam to an object.
- 48. (Original) The computer readable medium of claim 47, wherein the performing the medical procedure comprises adjusting a delivery of the radiation beam based on the treatment data.
- 49. (Original) A method of performing physiological gating in a medical procedure, comprising:

providing a template;

acquiring an input image of a target region;

registering the input image with the template;

determining a position of the target region based on the registering; and gating a medical procedure based on the determined position of the target region.

- 50. (Original) The method of claim 49, further comprising enhancing a moving object in the input image.
- 51. (Original) The method of claim 50, wherein the enhancing comprises subtracting an average of previously acquired input images from the input image.
- 52. (Original) The method of claim 49, wherein the registering comprises selecting the template from a plurality of templates that best matches an image in the input image.
- Original) The method of claim 52, wherein the determining the position of the target region comprises determining a position of the image in the input image that best matches with the template.
- 54. (Original) The method of claim 49, wherein the medical procedure comprises a radiation treatment, and the gating comprises activating or deactivating a radiation beam based on the determined position of the target region.

55. (Original) A system for performing physiological gating in a medical procedure, comprising:

means for providing a template;

means for acquiring an input image of a target region;

means for registering the input image with the template;

means for determining a position of the target region based on the registering; and means for gating a medical procedure based on the determined position of the target

- 56. (Original) The system of claim 55, wherein the means for registering comprises means for selecting the template from a plurality of templates that best matches an image in the input image.
- Original) The system of claim 55, wherein the medical procedure comprises a radiation treatment, and the means for gating comprises means for activating or deactivating a radiation beam based on the determined position of the target region.
- 68. (Original) A computer readable medium having a set of stored instructions, the execution of which causes a process to be performed, the process comprising:

providing a template;

acquiring an input image of a target region;

registering the input image with the template;

region.

determining a position of the target region based on the registering; and gating a medical procedure based on the determined position of the target region.

- 59. (Original) The computer readable medium of claim 58, wherein the process further comprising enhancing a moving object in the input image.
- 60. (Original) The computer readable medium of claim 59, wherein the enhancing comprises subtracting an average of previously acquired input images from the input image.
- 61. (Original) The computer readable medium of claim 58, wherein the registering comprises selecting the template from a plurality of templates that best matches an image in the input image.
- 62. (Original) The computer readable medium of claim 58, wherein the determining the position of the target region comprises determining a position of the image in the input image that best matches with the template.
- 63. (Original) The computer readable medium of claim 58, wherein the medical procedure comprises a radiation treatment, and the gating comprises activating or deactivating a radiation beam based on the determined position of the target region.

- 64. (Previously Presented) The method of claim 1, wherein the act of acquiring the sequence of images is performed during a treatment session.
- 65. (Previously Presented) The system of claim 10, wherein the means for acquiring the sequence of images is configured to acquire the sequence of images during a treatment session.
- 66. (Previously Presented) The computer readable medium of claim 15, wherein the act of acquiring the sequence of images is performed during a treatment session.

REMARKS

Amendments to claims 24, 34, and 40 are to incorporate a limitation from canceled claim 30. Amendment to claim 31 is to change claim dependency. No new matter has been added.

Applicant wishes to thank the Examiner for withdrawing the previous rejection under § 103.

I. Claim Rejections under 35 U.S.C. § 103 based on Kaufman and Takeo

Claims 1-23 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 7,006,862 (Kaufman) in view of U.S. Patent No. 6,125,166 (Takeo).

Claims 1, 10, and 15

Claim 1 recites gating a medical procedure based on the first composite image (wherein the first composite image is determined based on first and second images that are real-time images). Claims 10 and 15 recite similar limitations. Kaufman does not disclose or suggest gating a medical procedure based on the composite image as described in the claims. Rather, Kaufman discloses a method of gating image scans to obtain projection image(s) (13:65-14:39). In particular, Kaufman discloses a self-gating method (14:10-24), in which images that correspond to the heart being in diastole are selected (14:22-24), and the selected images are then used to form the coronal/sagittal projection image (14:36-39). Thus, Kaufman actually discloses gating a selection of images, and using the selected images to determine a projection image. To the extent that the projection image of Kaufman is analogized as the claimed "composite image," Applicant respectfully notes that Kaufman does not disclose or suggest obtaining a composite image first, and then gating a medical procedure based on such composite image, but rather, the

gating in Kaufman is performed first in order to obtain such composite image (which is the opposite of what is claimed in that sense).

Takeo also does not disclose or suggest the above limitation, and therefore fails to make up the deficiency present in Kaufman. In particular, Takeo discloses a method of forming an energy subtraction image, which is used for diagnosis of an illness (3:47-54), and not for gating a medical procedure.

For at least the foregoing reasons, claims 1, 10, and 15, and their respective dependent claims, are believed allowable over Kaufman, Takeo, and their combination.

Dependent claims 2-9, 11-14, 16-23, and 64-66

Applicant notes that the Office Action did not specifically identify where the elements of the dependent claims 2-9, 11-14, 16-23, and 64-66 are found, and that to the extent that these elements are found in the secondary reference Takeo, the Office Action did not provide a motivation to combine Takeo with Kaufman with respect to these elements. Under the rulings of the Supreme Court for *KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), the element being combined must be known, and that there must be a motivation to combine such element. Thus, Applicant respectfully submits that a prima facie case of the § 103 rejection has not been established for the above dependent claims, and requests that the § 103 rejection for these claims be withdrawn.

II. <u>Claim Rejections under 35 U.S.C. § 103 based on Kaufman, Takeo, and Verard</u>

Claims 24-66 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kaufman in view of Takeo, and further in view of U.S. Patent Application Publication

2004/0097805 (Verard).

Claims 24, 34, and 40

Claim 24 has been to recite providing a plurality of templates, each of the templates having an image and treatment data, wherein the treatment data comprises radiation treatment data (Emphasis added). Claims 34 and 40 have been amended to recite similar limitation regarding radiation treatment data. Applicant agrees with the Examiner that Kaufman and Takeo do not disclose or suggest providing templates that include both image and treatment data. According to the Office Action, paragraphs 112, 132, and 146 of Verard allegedly discloses templates that includes treatment data. However, these cited passages of Verard discloses that the templates may provide lead placement info and ablation zone info, neither of which is radiation treatment data. Notably, the ablation zone discussed in paragraph 146 of Verard is for ablation of tissue using a lead (see paragraph 72, last sentence), and not radiation. For at least the foregoing reasons, claims 24, 34, and 40, and their respective dependent claims, are believed allowable over Kaufman, Takeo, Verard, and their combination.

Claims 49, 55, and 58

Claim 49 recites gating a medical procedure based on the determined position of the target region. Claims 55 and 58 recite similar limitations. Kaufman does not disclose or suggest the above limitation. Rather, Kaufman discloses gating a collection of images based on a size of the heart (14:10-24), and not based on a position of a target region. Takeo and Verard also do not disclose or suggest the above limitation, and are not being relied upon for the disclosure of the above limitation. Since none of the cited references discloses or suggests the above limitation, they cannot be combined to form the subject matter of claims 49, 55, and 58. For at

least the foregoing reasons, claims 49, 55, and 58, and their respective dependent claims, are believed allowable over Kaufman, Takeo, Verard, and their combination.

Dependent claims 25-29, 31-33, 35-39, 41-48, 50-54, 56, 57, and 59-63

Applicant notes that the Office Action did not specifically identify where the elements of the dependent claims 25-29, 31-33, 35-39, 41-48, 50-54, 56, 57, and 59-63 are found, and that to the extent that these elements are found in the secondary references, Takeo and Verard, the Office Action did not provide a motivation to combine Takeo and Verard with Kaufman with respect to these elements. Under the rulings of the Supreme Court for *KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), the element being combined must be known, and that there must be a motivation to combine such element. Thus, Applicant respectfully submits that a prima facie case of the § 103 rejection has not been established for the above dependent claims, and requests that the § 103 rejection for these claims be withdrawn.

CONCLUSION

Based on the foregoing remarks, all claims are believed allowable. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at the number listed below.

The Commissioner is authorized to charge any fees due in connection with the filing of this document to Bingham McCutchen's Deposit Account No. <u>50-4047</u>, referencing billing number VM7031422001. The Commissioner is authorized to credit any overpayment or to charge any underpayment to Bingham McCutchen's Deposit Account No. <u>50-4047</u>, referencing billing number VM7031422001.

Respectfully submitted,

Dated:	January 4, 2008	By: _	Coment	Ca
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